DECLARATION UNDER 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner Corrigan:

I, Dan Lieberman, M.D., declare as follows:

1. I am the Applicant for the patent application entitled "METHOD AND APPARATUS FOR IRRIGATION AND DRAINAGE OF THE BRAIN'S SUBDURAL SPACE USING A PERCUTANEOUS APPROACH," Ser. No. 10/646,903, filed August 22, 2003 and the inventor of the subject matter described and claimed therein.

2. I am a board certified neurosurgeon. I have been in practice since 2000. My practice includes the management of hundreds of patients with subdural hematomas, which are a routine occurrence in neurosurgical practice.

3. After a careful review of the prior art cited by the examiner, and based upon all of my years of experience in the field of neurosurgery generally and subdural hematomas specifically, the medical device cited by the examiner in the Wong et al is not used for the treatment of subdural hematomas. There are several important differences between the techniques for suctioning a hematoma and flushing the evacuated space with fluid as compared to the techniques for cooling or providing therapeutic substances. The Wong device is designed to simultaneously access two difference fluid spaces (the intraventricular space and the subarachnoid or subdural space) with the ability to rapidly cool fluid and push it from one space to another. Conversely, the dual-lumen catheter that is the subject of my patent application, is designed to irrigate and drain one space, not push fluid between spaces for other purposes, such as cooling. The Wong et al device is not suitable for the purpose of irrigating a subdural space and draining out a lesion or subdural hematoma. The Wong et al device could not be implanted in the subdural space due to its rigidity and size. Furthermore, it could not be left in the subdural space over an extended period of time. Each and every claim of the Wong et al. patent describe the use of a balloon, which would be dangerous and potentially fatal in the subdural space. A balloon is simply not suitable for the evacuation of a

subdural hematoma since it would increase rather than decrease the intracranial pressure created by a subdural hematoma.

4. I further declare that all statements made herein are of my own knowledge and all statements made on information or belief are believed to be true; and further that these statements are made with the knowledge that willful and false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the above-referenced application and any patent issuing therefrom.

FURTHER DECLARANT SAYETH NOT.

Dan Lieberman

Dan Lieberman, M.D.

5/14/09

Date